



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,525	02/27/2004	Richard James Cawthray	02911.012130.	7746
5514 7590 11/09/2010 FITZPATRICK CELLA HARPER & SCINTO 1290 Avenue of the Americas NEW YORK, NY 10104-3800				
EXAMINER				
ROBERTS, LEZAH				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
11/09/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/789,525

Applicant(s)

CAWTHRAY ET AL.

Examiner

LEZAH W. ROBERTS

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2010.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 11, 14, 25 and 26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 2, 4, 11, 14, 25 and 26 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on February 27, 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed September 8, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness

1) Claims 1, 2, 4, 11, 14, 25 and 26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Daifotis et al. (US 5,994,329) in view of Kelly (US 4,817,819) in further view of Palo Alto Medical Foundation (January 2002).

Applicant Arguments

Applicant argues the subject kit increases patient compliance and ease of administration. Since bisphosphonate and calcium should not be taken at the same time because the calcium interferes with the absorption of the active, the kit clearly teaches

patients to take the accompanying nutrient on days only when not taking the active, thereby avoiding any problems associated with simultaneous dosing.

Applicant argues Daifotis fails to specifically recite or suggest, by way of example, any regimens administering doses of a nutrient; fails to specifically identify vitamins, or, more specifically, vitamin D; fails to offer any guidance as to the amount of calcium or other nutrient that might be administered in unit doses in the kit and fails to appreciate the benefits achieved by taking a nutrient while eliminating the problems of simultaneous dosing of a nutrient and bisphosphonate, as recited in the present invention and explained above. Kelly does not teach administration of unit doses of accompanying calcium, vitamin D, or a nutrient of any kind. They merely teach that seven tablets in the blister pack might be a placebo or non-active tablet. Further, there is clearly no disclosure or suggestion of the amount of calcium, or vitamin D to be administered in the unit. Kelly does not teach or suggest avoidance of simultaneous daily dosing of the bisphosphonate and the nutrient, or the benefits achieved thereby, namely increased effectiveness of the active. Palo Alto Medical Foundation fails to remedy the deficiencies of Daifotis and Kelly. Palo Alto Medical Foundation fails to specify a kit containing an active ingredient, and fails to offer any guidance on the dosing of the active in relation to the supplement and the benefits that may be achieved by a kit whereby simultaneous dosing is avoided.

Examiner's Response

Daifotis et al. disclose the bisphosphonate may be provided in a kit for conveniently and effectively carrying out the methods in accordance with the present invention. Such a kit preferably includes a number of unit dosages. Such kits can include a card having the dosages oriented in the order of their intended use. An example of such a kit is a "blister pack". If desired, a memory aid can be provided, for example in the form of numbers, letters, or other markings or with a calendar insert, designating the days in the treatment schedule in which the dosages can be administered (col. 13, lines 47-67). Thus, the reference is suggesting the kit of the instant claims by disclosing that the unit dosages may be arranged in the order of their intended use. It also discloses a memory aid may be used so that a patient may not forget to take their medicine, which increase patient compliance. In regard to a patient simply not following instructions, it would appear that adding a memory aid would not affect this action if the patient does not want to follow instructions. In regard to Daifotis et al. not disclosing vitamins, Daifotis et al. do disclose "placebo dosages or calcium or dietary supplements, either in a form similar to or distinct from the bisphosphonate dosages, can be included to provide a kit in which a dosage is taken everyday" (col. 13, lines 47-67). This suggests that the bisphosphonate is not taken on the same day as the supplement and the supplement replaces the bisphosphonate in order to keep the patient on a routine schedule to decrease the likelihood of a patient missing a dosage of medicine. This is supported by the teachings of Kelly, which also discloses this type of regimen. Therefore, the bisphosphonate and the calcium, vitamin D or mixtures thereof are not taken on the same day, meeting the limitations of the amended claims. In regard

to Daifotis et al. not teaching vitamins or vitamin D, the claims read on calcium, vitamin D or a mixture, thus vitamin D is not required for the independent claim. Even if vitamin D was required, Daifotis suggests supplements and Palo Alto Medical Foundation provides motivation as to why one of ordinary skill in the art would want to use a mixture of calcium and vitamin D as the supplement suggested by Daifotis et al. This is to insure calcium absorption. In regard to the amounts, Palo Alto Medical Foundation discloses dosages of calcium and vitamin D recommended for body function including bone growth and maintenance. Thus it is reasonable to conclude that one of ordinary skill in the art would follow these dosages and use them in the kits of Daifotis in order to maintain or obtain the desired body function of bone growth and maintenance.

2) Claims 1, 2, 4, 11, 14, 25 and 26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Daifotis et al. (US 5,994,329) in view of Allendorf et al. (US 5,265,728) in further view of Palo Alto Medical Foundation (January 2002).

Applicant's Arguments

See Applicant's Arguments above in regard to Daifotis et al. and Palo Alto Medical Foundation. Applicant also makes the same argument for Allendorf et al. as those above for Kelly.

Examiner's Response

See Examiner's Response above in regard to Daifotis et al. and Palo Alto Medical Foundation. In regards to Allendorf et al., the response applied to Kelly above,

also apply to Allendorf et al. Allendorf et al. supports the suggestion of using a placebo in order to keep the patient on a routine schedule to decrease the likelihood of a patient missing a dosage of medicine. Thus the rejection is maintained.

Conclusion

Claims 1, 2, 4, 11, 14, 25 and 26 are rejected.

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612
/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612